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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,983	01/09/2001	Salvatore Albani	031544.0004.CIP	6818

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 07/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/756,983	Applicant(s) Albani
	Examiner G.R. Ewoldt	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-11 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3 and 5, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, MHC components, antigen components, and accessory molecule components, classified in Class 424, subclass 93.1.

II. Claim 4, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, MHC components, antigen components, accessory molecule components, and co-stimulatory molecules, classified in Class 424, subclass 93.1.

III. Claim 4, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, MHC components, antigen components, accessory molecule components, and adhesion molecules, classified in Class 424, subclass 93.1.

IV. Claim 4, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, MHC components, antigen components, accessory molecule components, and cell modulation molecules, classified in Class 424, subclass 93.1.

V. Claims 6-8 and 10, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, tetravidin components, MHC components, antigen components, and accessory molecule components, classified in Class 424, subclass 93.1.

VI. Claim 9, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, tetravidin components, MHC components, antigen components, accessory molecule components, and co-stimulatory molecules, classified in Class 424, subclass 93.1.

VII. Claim 9, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, tetravidin components, MHC components, antigen components, accessory molecule components, and adhesion molecules, classified in Class 424, subclass 93.1.

VIII. Claim 9, drawn to an artificial APC comprising liposome components, GM-1 components, cholera toxin β components, tetravidin components, MHC components, antigen components, accessory molecule components, and cell modulation molecules, classified in Class 424, subclass 93.1.

IX. Claim 11, drawn to a method of modulating antigen specific T cells, classified in Class 424, subclass 93.1.

2. Inventions I-VIII are different products. The products comprise different components with different immunological properties. For example, the addition of co-stimulatory components would significantly alter the composition's immunostimulatory capacity whereas the addition of adhesion components might alter the composition's immunolocalizing properties. Therefore the methods are patentably distinct.

3. Inventions I-VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in materially different processes, such as for *in vitro* assays.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
July 25, 2002